

IN THE CLAIMS

Cancel claim 15 and non-elected claims 36-38.

Please replace claims 1, 6, 20, 26, 29, 35, and 40 - 54 with the following

claims:

Subt
B1
A2
1. (Amended) A solid pharmaceutical composition for parenteral injection, said composition having the shape of a needle capable of penetrating cutis or mucosa, comprising a binder and at least one therapeutic agent, said binder constituting at least 0.5% by weight of the composition and said binder comprising at least one binding agent being a carbohydrate, and said therapeutic agent comprises at least 25% by weight of the composition and said composition comprising at least one non-crystallisation agent, whereby said binder forms an amorphous matrix, and whereby such composition is injectable without dissolution or other reconstitution.

A3
6. (Amended) The composition according to claim 1, wherein the binder essentially remains an amorphous matrix for at least 6 months at ambient temperature.

A4
20. (Amended) The composition according to claim 1, wherein the at least one binding agent being a carbohydrate is a mono-, di-, or oligosaccharide or a corresponding sugar alcohol.

A5
26. (Amended) The composition according to claim 1, wherein the binding agent is maltitol and the non-crystallization agent is sorbitol and/or sugar alcohol of maltotriose and higher oligosaccharides.

29. (Amended) The composition according to claim 1, wherein the viscosity of the composition is less than 50,000 Pa*s in a sub-range of a temperature interval between 60 and 140°C.

35. (Amended) The composition according to claim 1, wherein the therapeutic agent is selected from hormones, antidiabetic drugs, growth factors, and blood factors.

40. (Amended) A method for preparing a solid pharmaceutical composition for parenteral injection comprising mixing at least one therapeutic agent homogeneously with a binder, obtaining an amorphous melt matrix, wherein the binder comprises at least one binding agent being a carbohydrate and at least one non-crystallisation agent, said binder constituting at least 0.5% by weight of the composition and at most 75% by weight of the composition, and said therapeutic agent comprising at least 25% by weight of the composition, shaping the melt to a predetermined needle geometry, cooling to below the T_g (glass transition temperature) of the binder obtaining the composition, and removing the composition from a mold cavity.

41. (Amended) The method according to claim 40, wherein the melt is injected into a mould cavity having a predetermined geometry.

42. (Amended) The method according to claim 40, further comprising a heating step to obtain the amorphous matrix prior to mixing the composition.

43. (Amended) The method according to claim 40, wherein prior to melting

the binder is dissolved in a solvent, dried, obtaining a solid amorphous matrix, and disintegrating the binder into a powder.

44. (Amended) The method according to claim 40, wherein the binder and the at least one therapeutic agent are mixed homogeneously as powders and melted to form the melt afterwards.

45. (Amended) The method according to claim 43, wherein the solvent is water.

46. (Amended) The method according to claim 40, wherein the water content of the composition is less than 20% by weight.

47. (Amended) The method according to claim 40, wherein the Tg of the binder is at least 30°C.

48. (Amended) The method according to claim 40, wherein the viscosity of the composition is less than 50,000 Pa*s in a sub-range of a temperature interval between 60 and 140°C.

49. (Amended) The method according to claim 40, wherein the steps of the method are carried out essentially aseptically.

50. (Amended) The method according to claim 40, wherein the composition is molded as the second part in a two component molding machine.

51. (Amended) The method according to claim 50, wherein a cartridge constituting the mold cavity is molded as the first part in a two component molding machine.

52. (Amended) The method of injecting the solid pharmaceutical composition recited in claim 1 through an epidermis or mucosa of an animal comprising arranging a device comprising the solid composition adjacent the epidermis or mucosa and ejecting the solid composition.

53. (Amended) The method according to claim 52, wherein the animal is selected from the group of fish, birds, molluscs, reptiles or mammals.

54. (Amended) The method according to claim 52, wherein the composition is injected at least once a day.

Add the following claim:

59. The method according to claim 52, wherein the animal is man.
